

FBS Cell Culture Media and Reagents

CORNING



B₂? B2BIO

비투바이오(주)

★ 타사제품 비교 최저 수준의 Endotoxin Level :

- » 기준값 : 0.25 EU/ml 이하, 결과값 : 0.005~0.001 EU/ml
- » cGMP 생산시설에서 FDA기준을 적용하여 생산합니다.
- » WFI 기준의 High Quality Water사용합니다.

★ USP(미국약전) 기준의 WFI Water 사용 :

- » Cellgro의 전제품은 **WFI(Water For Infection) Water**를 사용하여 만들어집니다.
- » **WFI Water**의 TOC(Total Organic Carbon)수치는 100ppb 이하입니다(ppb: 10^{-9} 단위)

★ Mycoplasma 테스트 :

- » 전제품에대해 100% Mycoplasma 테스트를 수행합니다.
(타사제품은 Animal origin제품에 대해서만 Mycoplasma test 수행)
- » Cellgro 전제품의 Specification(제품상세서)에 Mycoplasma test 결과를 명기합니다.

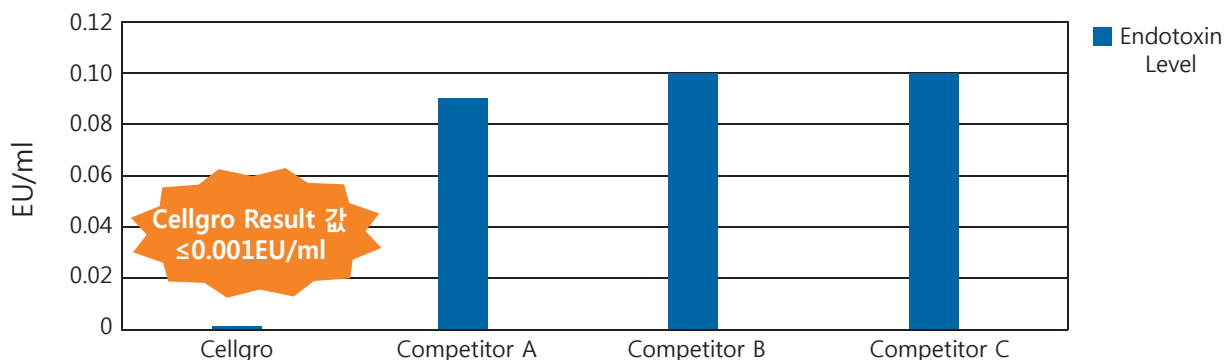
★ FDA 기준치 이하 멸균 처리 :

- » FDA 가이드라인 준수 (Class 1 Medical Device)
- » cGMP시설에서 생산
- » SAL(Sterility Assurance Level) 10^{-3} 기준치 이하 멸균
- » SAL(Sterility Assurance Level) 10^{-6} 기준치 이하 자동병입
- » SAL(Sterility Assurance Level) 10^{-8} 기준치 이하 자동주입 (Flexible containers)

★ cGMP, ISO 13485:2003 certified:

- » cGMP 기준 생산시설
- » ISO 13485:2003 Certified (Medical Device Management system)
- » ISO 17025:2001 compliant (Precision, accuracy, repeatability test)
- » 세계적인증기관인 TÜV승인

★ 타제품과의 Endotoxin Level 비교(DMEM / Result 값 기준)



*상기 비교표는 임의의 특정 Lot에 대해 비교한 수치입니다.

Nutrition Facts

Serving Size = 1 mL

Endotoxin Level	≤ 0.25 EU/mL
USP Sterility	< 1/100,000
SAL	10 ⁻⁶ bottles 10 ⁻⁸ flexible containers
Mycoplasma	Negative
WFI	TOC < 100 ppb

FDA Regulations

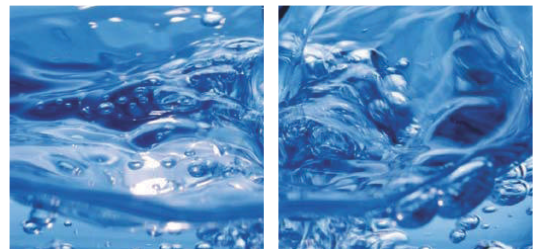
-21CFR Parts (210 and 211)	compliant
-21CFR Part (820)	compliant
-21CFR Part (606)	compliant
-21CFR Part (11)	compliant

ISO Designation

-13485:2003	certified
-14644	compliant
-17025:2000	compliant

Percent Daily Value - Quality, reliability, consistency

Ingredients - Water For Injection (WFI), Multicompendial Raw Materials (Amino Acids, Salts, Vitamins), Validated Quality



Certificate of Analysis

Description: DMEM, 1X
(Dulbecco's Modification of
Eagle's Medium)
with 4.5 g/L glucose,
L-glutamine & sodium
pyruvate

Catalog #: 10-013-CM
Lot #: 10013592
Expiration Date: 02/14
Country of Origin: USA

Storage: 2-8°C.

Notes:

Mediatech, Inc. products are prepared by a validated aseptic sterile filtration process to ensure that all products comply with the industry's **Sterility Assurance Level (SAL) of at least 10^{-3}** (i.e. demonstrating that a product produced in this manner has no more than 1 random contaminant per 1000 units).

This product was tested in accordance with currently approved Mediatech, Inc. specifications and procedures. Testing procedures are maintained in compliance with the current versions of the **USP and/or EP**, where applicable.

For IVD, Manufacturing and Research Uses Only. Utilization of this product apart from the labeled intended use may be a violation of local and/or Federal Law.

TEST PARAMETERS	SPECIFICATION	RESULT
Cell Line		
PRK (Cellgrowth)	Pass	Pass
L929 (Cellgrowth)	Pass	Pass
NG-108 (Cellgrowth)	Pass	Pass
L929 (Cytotoxicity)	Pass	Pass
pH	7.2 ± 0.2	7.1
Osmolality	335 ± 30 mOsm/Kg H ₂ O	341 mOsm/Kg H ₂ O
Endotoxin	≤ 0.25 EU/mL @ FW	< 0.0010 EU/mL @ FW
Mycoplasma	Tested Negative	Negative
Sterility	Pass	Pass

For detailed information on Mediatech, Inc. testing procedures, please contact our Technical Services department at (800) CELLGRO (235-5476) or via email at techserv@cellgro.com.

Written By/Date:

Suleman 25 Sep 2012

Verified By/Date:

Khay 25 SEP 2012

CORNING Product List

FBS	
35-015-CV	FBS Premium
35-016-CV	FBS Premium -Heat Inactivated
35-070-CV	FBS Premium -Gamma-irradiated
35-071-CV	FBS Premium - Dialyzed
35-072-CV	FBS Premium - Charcoal-Stripped
35-073-CV	FBS Premium - IgG Stripped
35-074-CV	FBS Premium - Embryonic Stem Cell Tested
35-075-CV	FBS Premium - Tetracycline Negative
35-076-CV	FBS Premium - Australia Source
35-022-CV	Donor Calf Serum, US. Sourced
35-030-CV	Donor Horse Serum, US. Sourced
35-060-CI	Human AB Serum / 100ml

Buffered Salt Solutions		
DPBS	21-031-CVR	1x, w/o calcium & magnesium
	21-031-CMR	1x, w/o calcium & magnesium, 1L
	21-030-CVR	1x, w/ calcium & magnesium
	20-030-CVR	10x, w/ calcium & magnesium
	20-031-CVR	10x, w/o calcium & magnesium
PBS	21-040-CVR	1x, w/o calcium & magnesium
	21-040-CMR	1x, w/o calcium & magnesium, 1L
	46-013-CMR	10x, w/o calcium & magnesium
HBSS	20-021-CVR	10x, w/o sodium bicarbonate w/ phenol red
	20-023-CVR	10x, w/o phenol red, sodium bicarbonate
	21-020-CVR	1x, w/ calcium & magnesium
	21-023-CVR	1x, w/o phenol red

Classical Media		
DMEM High Glucose	10-013-CVR	w/ 4.5g/L glucose, Sodium pyruvate
	10-013-CM	w/ 4.5g/L glucose, Sodium pyruvate, 1L
	10-017-CVR	w/ 4.5g/L glucose, w/o Sodium pyruvate
	10-017-CM	w/ 4.5g/L glucose,w/o Sodium pyruvate,1L
DMEM Low Glucose	10-014-CVR	w/ 1.0g/L glucose,sodium pyruvate
DMEM-F12	10-090-CVR	50/50 Mix w/ L-glutamine
	10-092-CVR	50/50 Mix w/ L-glutamine & 15mM HEPES
RPMI 1640	10-040-CVR	1x, w / L-glutamine
	10-041-CVR	1x, w / L-glutamine & 24mM HEPES
Ham's F10	10-070-CVR	1x, w/ L-glutamine
Ham's F12	10-080-CVR	1x, w/ L-glutamine
MEM	10-010-CVR	1x, w/ Earle's salts & L-glutamine
	15-010-CVR	1x, w/ Earle's salts, w/o L-glutamine
MEM-Alpha	10-022-CVR	1x, w/ Earle's salts & L-glutamine
	15-012-CVR	1x, w/ Earle's salts, w/o L-glutamine
F-12K	10-025-CVR	F-12K Nutrient Mixture(Kaighn's Mod.)
McCoy's 5A	10-050-CVR	Iwakata & Grace Modification
Medium 199	10-060-CVR	1x, w/ Earle's salts & L-glutamine
Leibovitz's	10-045-CVR	Leibovitz's L-15(Mod.) w/ L-glutamine
MCDB 131	10-016-CVR	w/o L-glutamine
TransfectaGRO™	40-300-CVR	transfectaGRO Reduced Serum Medium
glutaGRO™ (L-glutamine 대신 L-glutamine의 dipeptide를 사용)		
DMEM High Glucose	10-101-CVR	glutaGRO™ DMEM w/ sodium pyruvate
	10-102-CVR	glutaGRO™ DMEM w/o sodium pyruvate
RPMI 1640	10-104-CVR	glutaGRO™ RPMI 1640 w/ phenol red

Trypsin (Enzymatic dissociation agents)		
Trypsin	25-053-CI	0.25% Trypsin EDTA, 1x
	25-052-CI	0.05% Trypsin EDTA, 1x
	25-050-CI	0.25% Trypsin, 1x
	25-054-CI	2.5% Trypsin, 10x
Accutase (Enzymatic dissociation agents)		
Accutase®	25-058-CI	Accutase® Cell Detachment Solution, Liquid

Cellstripper™ Non-enzymatic dissociation solution		
Cellstripper™	25-056-CI	non-enzymatic dissociation solution

Antibiotics and Antimycotics	
30-002-CI	Penicillin-Streptomycin Solution, 100X
30-009-CI	Penicillin-Streptomycin-L-Glutamine, 100X
61-238-RH	Ampicillin, sodium Salt 10g,
30-004-CI	Antibiotic-Antimycotic Solution
30-100-RB	Blasticidin S HCL, Powder
61-239-RI	Chloramphenicol, Powder
30-234-CI	G418 Sulfate, Liquid 100ml
61-234-RF	G418 Sulfate, Powder 1g
30-005-CR	Gentamicin Sulfate, Liquid
61-098-RA	Gentamicin Sulfate, Powder 100mg
30-240-CR	Hygromycin B Solution
30-006-CF	Kanamycin Sulfate, Liquid
61-241-RG	Neomycin Sulfate, Power
61-385-RA	Puromycin Dihydrochloride, Powder
61-088-RM	Streptomycin sulfate, Powder

CORNING Product List

Supplement		
L-Glutamin	25-005-CI	L-glutamine, liquid 100ml
	25-005-CV	L-glutamine, liquid 500ml
	61-030-RM	L-glutamine, powder 100g
	61-030-RO	L-glutamine, powder 500g
	61-030-RR	L-glutamine, powder 1000g
glutaGRO™	25-015-CI	glutaGRO(Dipeptide L-glutamin), Liquid
MEM Amino Acids	25-030-CIR	MEM Amino Acids w/o L-glutamine 50x
	25-025-CIR	MEM Nonessential Amino Acids 100x
MEM Vitamin	25-020-CIR	MEM Vitamins 100x
ITS	25-800-CRR	Insulin-Transferrin-Selenium(ITS), 100X
HAT	25-046-CI	Hypoxanthine, Aminopterin, Thymidine, 50X
DMSO	25-950-CQC	Dimethyl Sulfoxide (DMSO)
Glucose	25-037-CIR	45% Glucose Solution
Sodium	25-000-CIR	Sodium Pyruvate
Pyruvate		
Trace Elements	25-021-CI	Trace Elements A (1,000X)
	25-022-CI	Trace Elements B (1,000X)
	25-023-CI	Trace Elements C (1,000X)
Trypan Blue	25-900-CI	Trypan Blue Solution 100ml

Buffers		
HEPES	25-060-CI	HEPES, Liquid
	61-034-RO	HEPES, Powder, 500g
Sodium Bicarbonate	25-035-CI	Sodium Bicarbonate, Liquid
	61-065-RO	Sodium Bicarbonate, powder 500g

Water	
25-055-CV	WFI(water for injection)-quality water 500ml
25-055-LH	WFI(water for injection)-quality water 200L
46-000-CV	Molecular Biology Grade Water 500ml

Serum-Free & Speciality Media	
40-101-CV	Corning® SF Medium with L-glutamine and 1g/L BSA / for hybridoma, 부유, 부착세포 / 500ml
40-102-CV	Corning® SF Medium with L-glutamine and 1g/L BSA without phenol red / for hybridoma, 부유, 부착세포 / 500ml
40-200-CV	Corning® PF Medium with out L-glutamine / for CHO cell
62-450-RF	rhAlbumin : Recombinant human serum albumin / 1g
40-300-CV	Corning® transfectaGRO Reduced Serum Medium / 500ml
40-410-KIT	Corning® stemgro hMSC Medium : defined medium for efficient expansion of hMSC on Corning CellBIND® Surfaces
40-550-CV	Corning® Hepatocyte Maintenance Medium / For the cultivation of hepatocytes
40-215-CV	Corning® hybriGRO SF™- w/ Corning® glutaGRO™ Supplement / for variety of hybridoma cell line
25-072-CV	Lymphocyte Separation Medium 500ml

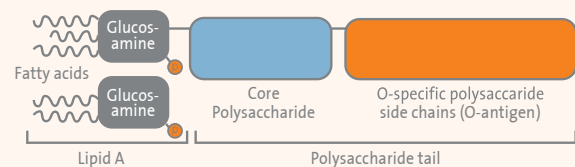
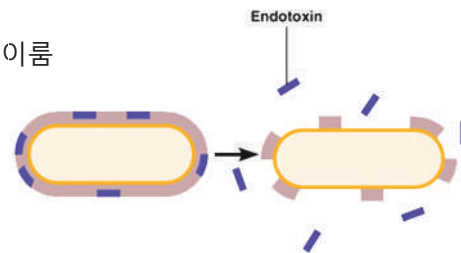
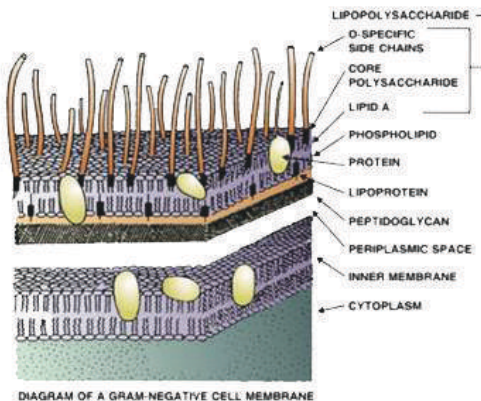
Insect Media and Reagents	
13-200-CV	Grace's Insect Basal Medium(Vaughn Mod.)
13-901-CI	Poloxamer 188
61-161-RM	Poloxamer 188, Powder
13-402-CV	Corning® Insectagro® DS2 Serum-Free/ Protein-Free Medium, 1X, w/o L-glutamine
13-410-CV	Corning® Insectagro® DS2 Serum-Free/ Protein-Free Medium, 1X, w L-glutamine
61-231-RO	Yeast Extract, Powder, 500g

Islet Solutions	
98-021-CV	Miami Medium #1A
98-291-CV	CMRL 1066 with HEPES, w/o sodium bicarbonate and phenol red

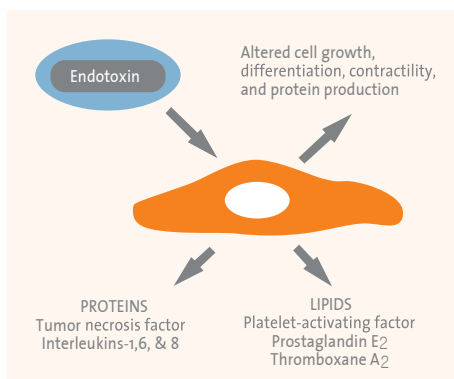
상기 제품리스트 외에도 Corning®은 Cell culture를 위한 다양한 제품을 확보하고 있습니다. 홈페이지를 참조하십시오.
www.cellgro.com

What is Endotoxin?

- » 그람음성균에 존재하는 내독소를 말함
- » Gram-negative bacteria의 외벽인 complex lipopolysaccharide(LPS)를 지칭하며 크게 3부분으로 나누어짐 : lipid A, core-oligosaccharide, O-antigen
- » 하나의 bacteria는 대략 200만 LPS로 구성되어 있으며, 박테리아 사멸시 대량의 endotoxin을 방출함
- » 열에 매우 안정함(250°C 30min, 180°C 1hour)
- » Endotoxin monomer는 매우 작지만(10kDa) 응집되어 1,000kDa 이상의 거대구조를 이룸
- » Toxic effect part : lipid A
- » Hydrophobicity : plasticware, glassware와 강한 결합을 이룸

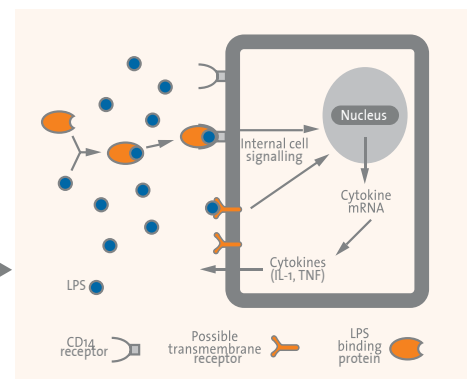


Endotoxin Effects & Mechanisms



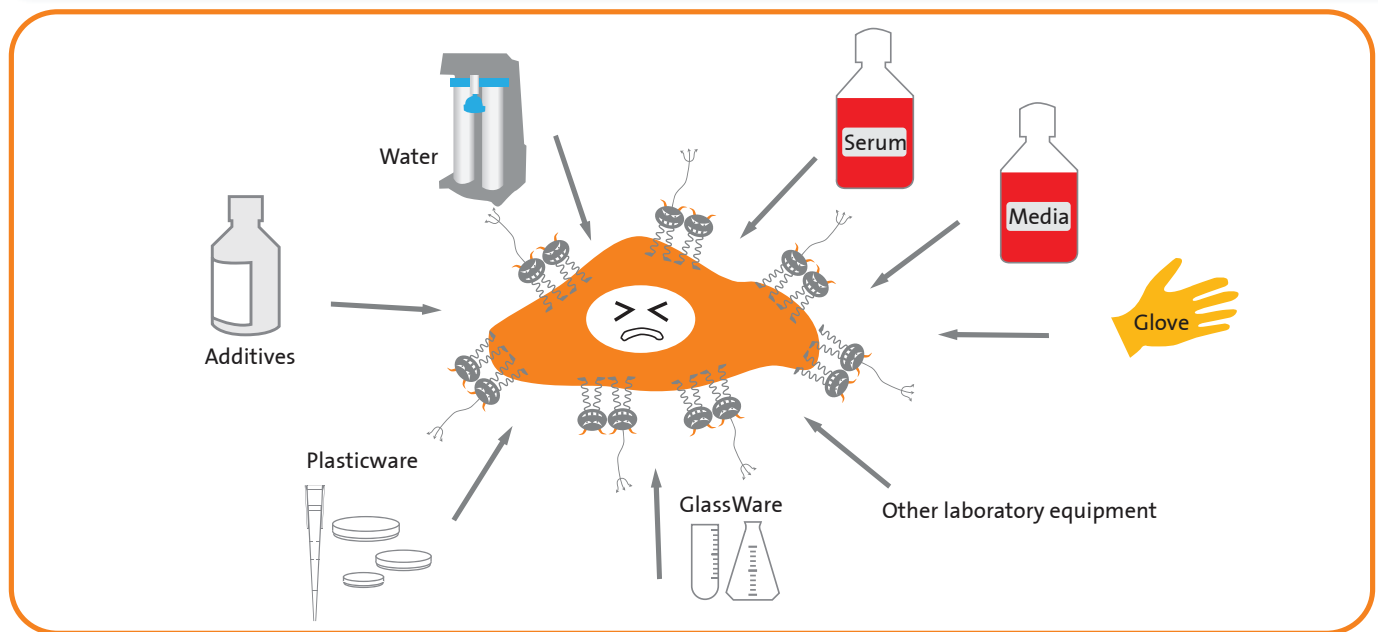
Depending on cell type and culture conditions, endotoxin can have a variety of effects on cell growth and function

One of the proposed models for endotoxin activating cells (Adapted from 14). The LPS binds to a LPS binding protein (LBP) forming a complex which interacts with a membrane anchored CD14 receptor. This results in the generation of an intracellular signal that turns on cytokine production (TNF = Tumor necrosis factor; IL-1 = Interleukin-1).

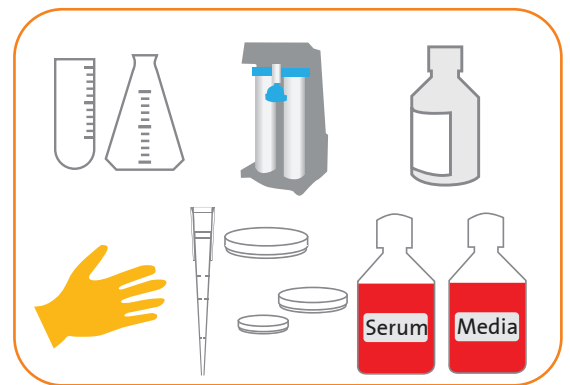


- » **Endotoxin은 그람음성균의 세포막의 구성성분 이기 때문에 cell culture시 cell membrane의 구조와 기능에 영향을 주게됨 (Clearly of critical concern in cell based research)**
- » Interaction with specific receptors on immune cells such as monocytes, macrophages, dendritic cells, and others such as cytokines, nitric oxide, and eicosanoids. ([Wikipedia, the free encyclopedia Oct. 2012](#))
- » Stimulation of leukocyte cultures to produce tissue factors, the activation of murine macrophages, and the inhibition of murine erythroid colony formation by very low level of endotoxin, increase the production of interleukin-6 in equine peritoneal macrophages ([J. Ryan, Ph.D. "Endotoxins and cell culture" Corning Technical Bulletin 2008](#))
- » Morphological change, morphological damage, influence of cytokine production, potent stimulus for tumor necrosis factor(TNF) production, stimulated or enhanced include prostaglandin, acid phosphatase, fibrinolytic inhibitor, collagenase production, nerve growth factor, secretion of factor B, polypeptides, platelet activating factor, adhesion inhibitor, adhesion molecule-1& procoagulant(dose dependent) Inhibitory effects for angiotensin converting enzyme activity, and synthesis of proteoglycan and alpha2 macro globulin .powerfull mitogens to some mammalian cell types, can inhibit or cell division, stimulate mitosis, can influence upon adherence, decreased insulin binding and endocytosis, loss of TNF binding sites, Protection from HIV infection, tumoricidal activity and increased in potassium current and in the number of potassium channels ([Michael E. Dawson, Ph.D. LAL Update, the significance of Endotoxin to Cell Culture and Biotechnology. 1998](#))

Sources of Endotoxin Contamination



Entotoxin Source	endotoxin level
Serum	0.06 EU/mL ~ 80 EU/mL
Media	0.001 EU/mL ~ 1 EU/mL
Additives	BSA : 1 EU/mL ~ 120 EU/mL
	Erythropoietin : 800 EU/mL ~ 20,000 EU/mL
	1 Molar amino acid solution : 500 EU/mL (최고치)
Glassware	250도에서 30분 또는 180도에서 3시간 가열 필요
Plasticware	0.007 EU/mL ~ 15 EU/mL (50ml conical tube)
	Pyrogen free Tip, MCT tube 사용 필요
Water	0.0010 EU/mL (Corning Cellgro™) ~



Some of the Documented In Vitro Effects of Endotoxin

Cell Type	Concentration (ng/mL)*	Endotoxin Effects
Equine macrophages	0.5	Induced production of IL-6 (11)
Human IVF embryos	1	Reduced pregnancy success rates in in vitro fertilization programs 3-4 fold (7,21)
Aortic rings	1	Reduced contractility and induced production of IL-1 and TNF (10)
Aortic endothelium	10	Dose dependent alterations in heparin sulfate proteoglycan production (3)
Murine B lymphomas	10	Increased production of immunoglobulin light chains 30-40 fold (20)
Recombinant CHO	10	Altered protein production (6)
Cardiac myocytes	10	Induced contractile dysfunction (23)
Human T Cells	100	Induced proliferation and lymphokine production in presence of monocytes (9)
Uretal epithelium	5000	Altered clonal efficiency (25)

*Lowest concentration of endotoxin that showed the effect.

Beginning-to-End Cell Culture Solutions From Corning

CORNING



Corning의 완벽한 세포배양 Solution

Corning은 최고 수준의 바이오제품 생산제조시설을 이용해 광범위한 실험실 기자재를 제조하고 있습니다. 뿐만 아니라 세포배양과 관련된 시약인 cell culture media, basal salt solutions, antibiotics, sera, specialty media 도 함께 Corning이라는 브랜드로 제조하고 있습니다. 새로이 시작된 Corning은 조직 또는 세포배양과 관련한 다양한 표준화된 Media, 고객맞춤형 Media, 분자생물학 시약을 제공합니다. 위와 같이 Corning은 실험용 기자재 뿐만 아니라 세포배양과 관련된 시약을 갖추고 있어 연구원분들에게 세포배양과 관련된 모든 제품을 제공하게 됨을 기쁘게 생각합니다.



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